K090313

Smith & Nephew, Inc.
Summary of Safety and Effectiveness
PiGalileo Total Knee Replacement (TKR) CAS V4.1 and Base V2.3

MAR 11 2009

Contact Person and Address
Mandy Coe
Regulatory Affairs Specialist
Smith & Nephew Orthopaedics
1450 Brooks Road
Memphis, TN 38116
(901) 399-6277

Date of Summary: 02/05/2009

Name of Device: Smith & Nephew PiGalileo Total Knee Replacement (TKR) Software Applications CAS V4.1 and Base V2.3
Common Name: PiGalileo Total Knee Software

Device Description
The PiGalileo Navigation System is a software-controlled electromechanical stereotaxic device for computer aided navigation of PiGalileo surgical instruments with the purpose of assisting the surgeon in optimally positioning knee and hip prostheses during total knee and hip arthroplasties.

The PiGalileo TKR CAS V4.1 and Base V2.3 software applications are surgical techniques for computer assisted navigation that leverages PiGalileo Total Knee Replacement (TKR) instruments as well as a number of non-navigated knee instruments with the intent to optimally position knee prostheses during total joint arthroplasty.

Device Classification
21 CFR 882.4560 Stereotaxic Instrument – Class II

Indications for Use
The Smith & Nephew PiGalileo Total Knee Replacement (TKR) system is intended to be used in computer assisted orthopedic surgery to aid the surgeon with bone cuts and implant positioning during joint replacement. It provides information to the surgeon that is used to place surgical instruments during surgery utilizing anatomical landmarks and other data specifically obtained intra-operatively (e.g. ligament tension, limb alignment, etc.).

Examples of surgical procedures include but are not limited to:

- Total knee replacement supporting bone referencing technique
- Total knee replacement supporting ligament balancing technique
- Minimally invasive total knee replacement

Substantial Equivalence Information
The overall software design and the instruments used with Smith & Nephew PiGalileo Total Knee Replacement (TKR) CAS V4.1 and Base V2.3 software applications are substantially equivalent to the previously cleared applications listed below:

Manufacturer	Description	510(k)	Clearance Date
Smith & Nephew, Inc.	PiGalileo TKR Base V2.1 / CAS V4.0	K082267	10/29/08

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2009

Smith & Nephew, Inc.
% Mandy Coe
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K090313
Trade/Device Name: PiGalileo Total Knee Replacement (TKR) Software Applications CAS V4.1 and Base V2.3
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: OLO
Dated: February 6, 2009
Received: February 9, 2009

Dear Mandy Coe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K090313

Device Name: PiGalileo Total Knee Replacement (TKR) Software Applications CAS V4.1 and Base V2.3

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Prescription Use		AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)	X		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090313